PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xalkori Prior Authorization Policy
- Xalkori® (crizotinib capsules – Pfizer)

REVIEW DATE: 12/16/2020; 01/27/2021 selected revision

OVERVIEW

Xalkori, an oral kinase inhibitor, is indicated for the treatment of patients with:[1]

- **Non-small cell lung cancer (NSCLC)**, whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
- **NSCLC,** metastatic, whose tumors are ROS1-positive.
- **Anaplastic large cell lymphoma (ALCL)**, treatment of pediatric patients ≥ 1 year of age and young adults with relapsed or refractory, systemic ALCL that is *ALK*-positive.
  Limitations of Use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic *ALK*-positive ALCL.

Rearrangements involving the ALK locus on chromosome 2p33 have been documented in approximately 50% of inflammatory myofibroblastic tumors (IMTs).[7] IMTs occur primarily during the first two decades of life and typically arise in the lung, retroperitoneum, or abdominal region. Sustained partial response to Xalkori in a patient *with* ALK-translocated IMT, and no observed activity in a patient *without* ALK translocation have been reported. In another case report, a 45-year old Hispanic female was eventually diagnosed to have IMT with systemic involvement and ALK gene rearrangement.[8] The patient was treated with Xalkori and had a successful resolution of her lesions and symptoms. After a 27-month follow-up, the patient remained in complete clinical and radiologic remission.

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines:

- **NSCLC** (version 1.2021 – November 25, 2020), Alecensa® (alectinib capsules) is the preferred therapy (category 1).[2,5] Other recommended therapies include Zykadia™ (ceritinib capsules) and Alunbrig™ (brigatinib tablets) [both also category 1]. Xalkori (category 1 as well) is listed as Useful in Certain Circumstances. For subsequent therapy with progression on Xalkori, therapy can be switched to Zykadia, Alecensa, or Alunbrig (if not previously given) [all category 2A]. For progression on Alecensa, Alunbrig, or Zykadia, Lorbrena (lorlatinib tablets) is recommended (category 2A). Xalkori (Preferred) or Zykadia (Other Recommended therapy) are recommended as first-line therapy for ROS1 rearrangement-positive NSCLC (both category 2A). Lorbrena can be used as subsequent therapy for ROS1 rearrangement. Xalkori is also recommended as an emerging targeted therapy in patients with high level *MET* amplification or *MET* exon 14 skipping mutation in lung cancer (category 2A).
- **Soft tissue sarcoma** guidelines (version 1.2021 – October 30, 2020) recommend Xalkori as single-agent therapy for the treatment of IMT with ALK translocation (category 2A recommendation).[3,5]
- **T-Cell lymphoma** guidelines (version 1.2021 – October 5, 2020) recommend Xalkori use in ALK-positive anaplastic large cell lymphoma (ALCL) as a second-line and subsequent therapy option (category 2A) in patients with intent to proceed to transplant and in those who do not intend to proceed to transplant.[4,5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Xalkori. All approvals are provided for 3 years unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xalkori is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an approved test.

2. **Non-Small Cell Lung Cancer (NSCLC) with ROS1 Rearrangement.** Approve for 3 years if the patient has recurrent or metastatic disease as detected by an approved test.

3. **Anaplastic Large Cell Lymphoma.** Approve for 3 years if the patient meets the followring criteria (A, B, and C):
   - **A)** Patient were ≥ 1 year of age and ≤ 21 years of age; AND
   - **B)** Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   - **C)** Patient has received at least one prior systemic treatment regimen.
     Note: Examples of systemic treatment were Adcetris (brentuximab vendotin for injection) in combination with CHP (cyclophosphamide, doxorubicin, and prednisone), CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone).

Other Uses with Supportive Evidence

4. **Non-Small Cell Lung Cancer (NSCLC) with High Level *MET* Amplification or MET Exon 14 Skipping Mutation.** Approve for 3 years.

5. **Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation.** Approve for 3 years.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xalkori is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xalkori® capsules [prescribing information]. New York, NY: Pfizer Inc; January 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2021 – November 25, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 14, 2020.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2021 – October 30, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 14, 2020.

4. The NCCN T-Cell lymphomas Clinical Practice Guidelines in Oncology (version 1.2021 – October 5, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 25, 2021.
5. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on: December 14, 2020. Search term: crizotinib.

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